



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2013-0056; FRL- 9907-62]

Clomazone; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of clomazone in or on multiple commodities which are identified and discussed later in this document. In addition, this regulation removes an existing tolerance on “cabbage” that is superseded by this action. The Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the

SUPPLEMENTARY INFORMATION).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2013-0056, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal

holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Lois Rossi, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-7090; email address: *RDFRNotices@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2013-0056 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2013-0056, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of Wednesday, February 27, 2013 (78 FR 13295) (FRL-9380-2), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 2E8136) by the Interregional Research Project Number 4, IR-4 Project Headquarters, 500 College Road East, Suite 201 W, Princeton, NJ 08540. The petition requested that 40 CFR 180.425 be amended by establishing tolerances for residues of the herbicide clomazone, 2-[(2-chlorophenyl)methyl]-4,4-dimethyl-3-isoxazolidinone, in or on *Brassica*, head and stem, subgroup 5A at 0.1 parts per million (ppm), pea, southern, dry seed at 0.05 ppm, pea, southern, succulent seed at 0.05 ppm, pea, southern, hay at 0.05 ppm, and rhubarb at 0.3 ppm. In addition, the petitioner proposes based upon the establishment of new tolerances above, removal of the existing cabbage tolerance at 0.1 ppm under 40 CFR 180.425 that is superseded by this action. That document referenced a summary of the petition prepared by FMC Corporation, the registrant, which is available in the docket, <http://www.regulations.gov>. One comment was received on the notice of filing. EPA's response to the comment is discussed in Unit IV.C.

Based upon review of data supporting the petition, EPA has removed and/or established clomazone residue tolerances for certain commodities. The reason(s) for these changes are explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for clomazone including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with clomazone follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

The primary target of clomazone is the liver, with hepatocellular cytomegaly noted in the chronic rat and mouse studies (chronic mouse study deemed unacceptable due to maximum tolerated dose (MTD) not achieved), hepatocellular necrosis in the chronic mouse study, and increased liver weight observed in subchronic and chronic studies. No neurotoxicity studies with clomazone are available; however, based on a weight of the evidence approach, the EPA has concluded that a neurotoxicity battery is not required for clomazone. This approach considered all of the available hazard and exposure information including: (1) There is no evidence of clinical signs of neurotoxicity or neuropathology in adult animals in subchronic and chronic studies; (2) the liver is the target organ for clomazone, not the neurological system; (3) clomazone is absorbed and rapidly excreted in rats with 97% of the radioactivity excreted within 168 hours; and (4) the point of departure (POD) and endpoint for chronic dietary risk assessment is based on liver effects in rats which appear to be the most sensitive endpoint. There is no quantitative or qualitative evidence of susceptibility in the developmental toxicity study in rabbits or in the 2-generation reproduction toxicity study in rats. In the developmental toxicity study in rats, delayed ossification occurred at doses that produced maternal effects (chromorhinorrhea and abdominogenital staining). Although qualitative susceptibility was observed in the developmental toxicity study in

rats, the concern is low since there are clear no-observed-adverse-effect-levels (NOAELs) and lowest-observed-adverse-effect-levels (LOAELs) in the study and this study was used for risk assessment, and therefore, is protective of the developmental effects.

There is no concern for mutagenicity. In the rat carcinogenicity study, there was no evidence of carcinogenicity. The mouse carcinogenicity study was inadequate to determine carcinogenic activity due to the lack of adverse effects at the highest dose tested. Despite the inadequacy of the mouse carcinogenicity study, EPA has determined that an additional mouse carcinogenicity study is not needed and that the rat chronic/carcinogenicity study will be adequate for assessing chronic risk, including cancer. This finding is based upon the following conclusions: (1) The rat is more sensitive than the mouse for the chronic assessment; (2) the consistent effect in rats (decreased body weight and increased liver weight) has been used as the point of departure for the chronic assessment; (3) a new mouse study would only use doses well above the current POD for the chronic assessment; and (4) even if a new mouse study identified positive carcinogenicity effects, that finding would not result in the adoption of a quantitative linear assessment of cancer risk due to the negative carcinogenicity finding in the rat study and the lack of a positive finding for genotoxicity.

Specific information on the studies received and the nature of the adverse effects caused by clomazone as well as the NOAEL and the LOAEL from the toxicity studies can be found at <http://www.regulations.gov> in document, "Clomazone: Human Health Risk Assessment for New Uses in/on *Brassica*, Head and Stem, Subgroup 5A; Rhubarb;

and Pea, Southern (IR-4 Petition 2E8136)”, dated December 19, 2013, pg. 31 in docket ID number EPA-HQ-OPP-2013-0056.

B. Toxicological Points of Departure/Levels of Concern (LOC)

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological POD and LOC to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for clomazone used for human risk assessment is shown in the following Table of this unit.

Table -- Summary of Toxicological Doses and Endpoints for Clomazone for Use in Human Health Risk Assessment

| Exposure/Scenario | POD and Uncertainty/Safety Factors | RfD, PAD, LOC for Risk Assessment | Study and Toxicological Effects |
|-------------------|------------------------------------|-----------------------------------|---------------------------------|
|-------------------|------------------------------------|-----------------------------------|---------------------------------|

| | | | |
|---|---|---|---|
| Acute dietary (general population including infants and children) | An endpoint was not selected for the general population because no adverse effect in adult animals was identified that resulted from a single exposure. A risk assessment is not required for this population subgroup. | | |
| Acute dietary (females 13-49 years of age) | NOAEL = 100 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF = 1x | Acute RfD = 1.0 mg/kg/day aPAD = 1.0 mg/kg/day | Developmental toxicity study – rat, developmental LOAEL = 300 mg/kg/day, based on indications of delayed ossification in the form of either partial ossification or the absence of the manubrium, sternebrae 3-4, xiphoid, caudal vertebrae, and meta-carpals. |
| Chronic dietary (all populations) | NOAEL = 84.4 mg/kg/day (highest dose tested) UF _A = 10x UF _H = 10x FQPA SF = 1x | Chronic RfD = 0.84 mg/kg/day cPAD = 0.84 mg/kg/day | 2-year chronic toxicity study – rats, NOAEL = 84.4/112.9 mg/kg/day, males/females (highest dose tested), LOAEL was not attained co-critical 90-day oral rat study NOAEL = 135.2/160.9 mg/kg/day, males/females LOAEL = 273/319.3 mg/kg/day, males/females, based on decreased body weight, body weight gains, food consumption and increased absolute and relative liver weights in females and increased absolute liver weights in males. Co-critical 2-generation reproduction toxicity study parental NOAEL = 50 mg/kg/day parental LOAEL = 100 mg/kg/day based on statistically significantly decreased body weight & body weight gain during pre-mating, and decreased body weight during gestation & lactation M & F. In addition, |

| | | | |
|-----------------------------------|--|--|--|
| | | | decreased food consumption in females and hydronephritic kidneys in males. |
| Cancer (oral, dermal, inhalation) | The chronic endpoint is protective against any effects resulting from long-term exposure to clomazone. | | |

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). Point of Departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures.

C. Exposure Assessment

i. *Dietary exposure from food and feed uses.* In conducting the acute dietary exposure assessment EPA used the Dietary Exposure Evaluation Model - Food Consumption Intake Database (DEEM-FCID, ver. 3.16), which incorporates consumption information from the United States Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). As to residue levels in food, EPA incorporated tolerance level residues for proposed and registered crops, assumed 100 percent crop treated (PCT) and used default processing factors.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the DEEM-FCID, ver. 3.16 which incorporates consumption information from the USDA NHANES/WWEIA; 2003-2008. As to residue levels in food, EPA conducted an unrefined assessment that assumed 100 PCT, used DEEM default processing factors, and tolerance-level residues for all existing and proposed uses.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that the chronic PAD for clomazone will be protective of any cancer risk posed by the pesticide. Additionally, EPA is relying on the chronic dietary exposure assessment to evaluate cancer risk.

iv. *Anticipated residue and PCT information.* EPA did not use anticipated residue or PCT information in the dietary assessment for clomazone. Tolerance level residues and 100 PCT were assumed for all food commodities.

1. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for clomazone in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of clomazone. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

The Agency generated the surface water estimated drinking water concentrations (EDWCs) based on the Food Quality Protection Act (FQPA) Index Reservoir Screening Tool (FIRST) and the Tier 1 Rice Model. Screening Concentration in Ground Water (SCI-GROW) and Pesticide Root Zone Model Ground Water (PRZM GW) models were used for ground water EDWCs of clomazone. EDWCs were derived based on the maximum registered/proposed use rate (1.5 pound active ingredient per acre (lb ai/A) existing for tuberous and corm vegetables and proposed for rhubarb) and the maximum registered use rate on rice (dry-seeded 0.8 lb ai/A). The Tier 1 Rice model (dry-seeded scenario) produced the highest EDWCs for both acute and chronic exposure.

The EDWCs of clomazone for acute exposures are estimated to be 550 parts per billion (ppb) for surface water and 85.7 ppb for ground water.

For chronic exposures for non-cancer assessments are estimated to be 550 ppb for surface water and 77.4 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For both acute and chronic dietary risk assessment, the water concentration value of 550 ppb was used to assess the contribution to drinking water. These drinking water estimates account for parent plus FMC65317 (*N*-[(2-chlorophenyl)methyl]-3-hydroxy-2,2-dimethylpropanamide) which are the residues of concern in drinking water.

2. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Clomazone is not registered for any specific use patterns that would result in residential exposure.

3. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

EPA has not found clomazone to share a common mechanism of toxicity with any other substances, and clomazone does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has

assumed that clomazone does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* There was no evidence of increased quantitative or qualitative susceptibility in the prenatal developmental toxicity study in rabbits or in the reproductive toxicity study in rats with clomazone. In the developmental toxicity study in rats, effects in the fetuses (delayed ossification) occurred at doses that produced maternal effects (chromorhinorrhea and abdominogenital staining) but were qualitatively more severe. Although qualitative susceptibility was observed in the developmental toxicity study in rats, the concern is low since there are clear NOAELs and LOAELs in this study and the NOAEL in the study was used as the POD for assessment of acute risk. EPA's assessment of acute risk is therefore protective of any developmental effects.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

- i. The toxicity database for clomazone is complete.
- ii. Though there are no acute or subchronic neurotoxicity studies available for clomazone, there is no indication that clomazone is a neurotoxic chemical based on results of available subchronic, chronic, reproductive or developmental toxicity studies and no evidence of immunotoxicity. EPA concluded, based upon its assessment of available data, that acute and subchronic neurotoxicity studies are not required nor an additional uncertainty factor (UFs) needed to account for neurotoxicity.
- iii. For the reasons described above, there is low concern regarding increased susceptibility in the young from exposure to clomazone.
- iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to clomazone in drinking water. There are no existing or pending residential uses. Therefore, these assessments will not underestimate the exposure and risk posed by clomazone.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). Short-, intermediate-, and chronic-term risks are evaluated by comparing the

estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected for the general population including infants and children. Therefore, clomazone is not expected to pose an acute risk to these groups.

An acute endpoint was identified for females 13-49 years old due to effects observed in fetuses. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to clomazone will occupy 3.0 % of the aPAD for females 13-49 years old.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to clomazone from food and water will utilize 3.6 % of the cPAD for all Infants < 1 year of age, the population group receiving the greatest exposure. There are no residential uses currently registered or proposed for clomazone, and thus no chronic exposures from residential use of clomazone.

3. *Short-term and intermediate-term risk.* Short-term and intermediate-term aggregate exposures take into account short-term and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Clomazone is not registered for any use patterns that would result in short-term or intermediate-term residential exposures. Because there is no short-term or intermediate-term residential exposure and chronic dietary exposure has already been

assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short-term risk), no further assessment of short-term or intermediate-term risk is necessary. EPA relies on the chronic dietary risk assessment for evaluating short-term and intermediate-term risk for clomazone. Therefore, short-term and intermediate-term aggregate risk assessments are not required.

4. *Aggregate cancer risk for U.S. population.* Based on the data summarized in Unit III.A., EPA has concluded that the cPAD is protective of any cancer risk clomazone poses to humans. As noted above, chronic dietary exposure is 3.6 % of the cPAD for the highest exposed population subgroup.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to clomazone residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (gas chromatography (GC) using a nitrogen phosphorus detector (NPD) or mass spectrometer (MS)) is available to enforce the tolerance expression. Samples are acid hydrolyzed, hexane extracted, Na_2CO_3 washed, and cleaned-up with a Florisil column. The resulting samples are analyzed. The limit of quantitation (LOQ) for this method is 0.05 ppm. A confirmatory procedure (GC/MS-SIM) is available (Method I, PAM II).

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

There are no Codex MRLs for residues of clomazone.

C. Response to Comments

One comment was received from “American Citizen” indicating concerns over what he/she believes to be unacceptable toxic effects to human health, plants, and the environment if EPA approves the proposed new uses of clomazone. The commenter indicated a general opposition to the use of pesticides. The commenter also cited toxic effects shown in clomazone toxicity studies and the alleged irrelevance of chronic animal studies to chronic human exposure as grounds for denying the tolerance petition.

EPA’s response: The Agency has received similar categorical objections to the establishment of pesticide tolerances from several commenters on numerous previous occasions. Refer to **Federal Register** 70 FR 37686 (June 30, 2005), 70 FR 1354 (January 7, 2005), 69 FR 63096 (October 29, 2004) for the Agency’s response to these

types of comments. EPA disagrees with the commenter's assertion that a pesticide can cause toxic effects at high doses in animal studies necessarily means that a pesticide tolerance is unsafe. A determination on the safety of a tolerance must not only consider potential toxic effects of the pesticide but anticipated pesticide exposure levels as well. EPA's risk assessment did just that in finding that there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to clomazone. EPA also disagrees with the assertion that chronic animal studies are not relevant to assessing human risk. Chronic animal studies have been relied upon by national and international health agencies for over 50 years in evaluating risks to humans from exposure to chemical substances.

D. Revisions to Petitioned-For Tolerances

After reviewing supporting data and information, EPA modified certain elements of the petition as proposed in the notice of filing, as follows:

1. EPA corrected the proposed commodity definition, "*Brassica*, stem and head subgroup 5A" to read "*Brassica*, head and stem, subgroup 5A" for consistency in naming of commodities, and
2. In place of the proposed tolerance for "pea, southern, hay", EPA is establishing tolerances for "cowpea, forage", and "cowpea, hay" because pea, southern, hay is a very minor feed, where as "cowpea" is a type of "pea, southern".

V. Conclusion

Therefore, tolerances are established for residues of clomazone, 2-[(2-chlorophenyl)methyl]-4,4-dimethyl-3-isoxazolidinone, in or on *Brassica*, head and stem, subgroup 5A at 0.10 ppm; cowpea, forage at 0.05 ppm; cowpea, hay at 0.05 ppm; pea,

southern, dry seed at 0.5 ppm; pea, southern, succulent seed at 0.05 ppm; and rhubarb at 0.30 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption

provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: March 21, 2014.

Lois Rossi,
Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. Section 180.425 is amended by removing the entry for “Cabbage” from the table in paragraph (a), and by alphabetically adding the following entries

“*Brassica*, head and stem, subgroup 5A”, “Cowpea, forage”, “Cowpea, hay”, “Pea, southern, dry seed”, “Pea, southern, succulent seed”, and “Rhubarb” to the table in paragraph (a) to read as follows.

§ 180.425 Clomazone; tolerances for residues.

(a) *General.* * * *

| Commodity | Parts per million |
|--|-------------------|
| * | * * * |
| <i>Brassica</i> , head and stem, subgroup 5A | 0.10 |
| * | * * * |
| Cowpea, forage | 0.05 |
| Cowpea, hay | 0.05 |
| * | * * * |
| Pea, southern, dry seed | 0.05 |
| Pea, southern, succulent seed | 0.05 |
| * | * * * |
| Rhubarb | 0.30 |
| * | * * * |

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